# A Model for Adapting Clinical Guidelines for Electronic Implementation in Primary Care

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Medical informaticians who seek to implement clinical guidelines by computer must be aware of a significant gap that exists between guideline development and utilization. In order to be effective, guideline recommendations must be followed by clinicians: in order for clinicians to follow willingly, they must agree with the guidelines. This paper presents a model process for building consensus among clinicians that can be used to obtain support for guideline recommendations their prior to electronic implementation. This approach involves initial presentation of the guidelines by a specialist, iterative cycles of surveying clinicians' opinions about the guidelines and revising the guidelines, supervision of the process by a practice opinion leader, and final group discussion of the revised guidelines to reach consensus. This model was successfully used to adapt guidelines for the continuing care of patients with diabetes mellitus that were subsequently implemented electronically with broad support of the primary care clinicians using them. The model minimized the need for lengthy group discussion by surveying individuals' attitudes and working through a practice opinion leader to gain consensus support for the guidelines. efficient approach for developing support for guidelines among practitioners will facilitate the electronic implementation of guidelines and lead to enhanced compliance with guidelines after implementation.

# **INTRODUCTION**

In 1994, more than 1600 clinical practice guidelines were listed in the American Medical Association's guideline directory. In general, these guidelines have been developed to standardize the delivery of health care in an effort to reduce escalating health care costs without sacrificing quality [1-4]. Practice guidelines provide recommendations for appropriate care of patients in specific clinical circumstances [1]. However, the impact of clinical guidelines on health care is contingent upon widespread utilization: guideline utilization is contingent on effective dissemination [5]. Dissemination of guidelines through publication alone or in combination with educational programs was ineffective in improving compliance with guidelines [6,7]. Guideline dissemination can be greatly enhanced using computers to supply guideline recommendations to the point of care [8-13]. Such computerized guidelines have been shown to improve health care outcomes [14]. The potential impact of electronically implemented guidelines on the cost and quality of health care delivery, however, is undermined if the issue of clinician acceptance of guidelines is not addressed prior to implementation [6,12,15-17]. To date, insufficient attention has been given to the importance of clinician acceptance of guidelines prior to electronic implementation [2,18-20]. While some authors have suggested approaches for accommodating clinicians' attitudes in the development of future guidelines [21,22], little attention has been focused on improving clinician acceptance of the guidelines that already exist [19].

Clinician acceptance and utilization of guidelines is hindered by several factors [19,20,22,23]. First. most of the available practice guidelines have been created by specialists with little input from the primary care practitioners who are most often responsible for using them. Also, because physicians have historically functioned with little external regulation of their practice patterns, they often view guidelines as a threat to their autonomy. Similarly, guidelines are perceived to be inflexible when applied to the complexity of individual patient situations. Because few guidelines have been scientifically proven to maintain quality while controlling costs, clinicians often question the necessity for adherence to them, and argue that the potential increased expense of complying with guidelines is unjustifiable. Lastly, because guidelines exist for relatively few clinical scenarios, practitioners are unaccustomed to using them to direct patient management.

A method is needed to overcome clinician resistance to existing sets of guidelines prior to electronic implementation. A potential approach is through consensus building using group process. Vermeulen et al. [24] used an iterative systematic, questionnaire-mediated consensus building process (a modification of the Delphi method) to develop a set of clinical practice guidelines. Similar approaches. however, have not been used to adapt existing guidelines to facilitate acceptance. The purpose of this paper is to present a model for adapting existing care guidelines for electronic implementation. A case study illustrating the application of this model is presented. The process used in this case study is proposed as a model for use in other clinical settings and with other sets of care guidelines.

### METHODS AND PROCEDURES

# **Practice Setting**

The guideline adaptation model was developed at the Duke Family Medicine Center (DFMC), a free-standing family medicine clinic and setting for the Duke University Medical Center Family Medicine Residency Program. At the time of the study, the clinic employed 18 faculty primary care providers (14 family physicians, 1 general internist, 2 nurse practitioners, and 1 physician assistant) and 30 family medicine residents. No practice-wide standards for the continuing care of diabetic patients existed.

## Published Guidelines

As part of a larger project to evaluate the impact of the electronic implementation of guidelines on the quality and cost of continuing care of diabetic patients in a large primary care practice [13], it was recognized that an established set of care standards would need to be introduced into the practice. Standards of continuing care for patients with diabetes mellitus are published annually as a position statement by the American Diabetes Association (ADA) [25]. At the initiation of the project, the most recent guidelines had been approved in 1988. The ADA guidelines represent the opinions of experts on what constitutes optimal continuing care for patients with diabetes mellitus. These guidelines have been endorsed by several professional medical associations, but notably not by the American Academy of Family Physicians.

Therefore, the ADA guidelines were not suitable for electronic implementation at DFMC without adaptation. An approach was needed to adapt the ADA guidelines into a set of care standards that could be endorsed by all of the practitioners at DFMC. Universal acceptance of the guidelines was considered essential to ensure that disagreement with care

recommendations was not a factor affecting compliance with guidelines.

### A Model for Clinical Guideline Adaptation

A flow diagram of the model for the adaptation of published clinical guidelines is shown in Figure 1. The model draws upon a combination of the Delphi method [26], nominative group process and the use of an opinion leader. According to this model, a set of published guidelines is initially presented to the primary care providers by a domain specialist along with available scientific evidence demonstrating the individual cost-effectiveness of guideline recommendations. This presentation is followed by a survey of individual clinician practice patterns relative to the published guidelines. The survey asks each clinician to indicate if they "agree," "disagree," "strongly disagree," or have "no opinion" about each guideline recommendation. The survey also includes a section to elicit comments on how recommendations might be modified to make them more acceptable. A coded identifier is included on each survey so that clinicians who do not respond to the survey can be sent a duplicate survey. Survey results are then reviewed by the specialist and an opinion leader selected from the practice to develop the revised set of guidelines. An opinion leader is a member of a group who is recognized (either formally or informally) as an individual who influences practices and policies for the group at large. Previous work with guideline implementation has shown that an opinion leader can be a significant influence to modify clinician practice patterns [27]. The revised guidelines are then either presented at a clinical practice meeting for group discussion, or cycled through another survey of clinicians' opinions and further adaptation by the specialist and opinion leader. The decision to attempt to achieve consensus through group discussion versus

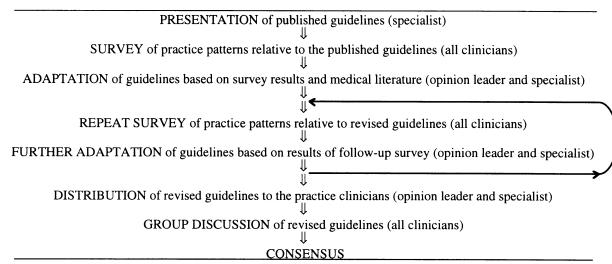


Figure 1. Model for Consensus Building for Clinical Guidelines in Primary Care.

re-survey of clinicians' opinions is guided by the degree of disagreement reflected in the survey results. If more than one provider "strongly disagrees" with a recommendation, a repeat cycle of re-surveying and revision was considered necessary. Individuals whose opinions were significantly different than their colleagues are invited to discuss their views with either the opinion leader, the specialist or both. Educational materials are made available as needed. The process may go though multiple iterations of re-survey and revision until the group opinion begins to converge and the opinion leader feels that consensus can be achieved with only limited group discussion. The most current iteration of the guideline recommendations is sent to the clinicians prior to the group meeting.

#### RESULTS

## Adaptation of Diabetes Mellitus Guidelines

The guideline adaptation process was initiated with a presentation of the current ADA guidelines to the 18 faculty clinicians by an endocrinologist. The faculty clinicians were selected as the target group because they set the standards for the resident physicians. The medical director for the clinic was selected as the opinion leader based on his position and on an informal survey of faculty providers regarding who influenced practice patterns within the clinic. The initial guideline presentation was followed by a survey of the faculty clinicians' practice patterns relative to eight ADA guideline recommendations (Table 1). The response rate to the survey was 100%. Out of the eight guideline recommendations, four received strong endorsement (item # 3,6,7,8) (agreement > 85%), two received moderate endorsement (item # 2,5) (agreement between 50-85%), and two evoked significant disagreement (item # 1,4) (agreement < 50%). Written comments generally requested reduction in the guideline expectations; however, a few clinicians requested more rigorous standards for some items. Survey responses were reviewed by the endocrinologist

and the opinion leader. A revised set of guidelines was created.

Revision of the initial guidelines led to the following modifications: 1) changing the requirement for foot exam from every visit to no more than monthly, and only in patients with known neuropathy or history of lower limb ulcers. At all other visits the foot exam was to be "suggested"; 2) changing renal function surveillance to dipstick urinalysis for protein and glucose instead of a complete urinalysis; 3) changing lipid surveillance to an annual cholesterol level instead of a complete lipid profile (total cholesterol, LDL, HDL, triglycerides); 4) changing the baseline electrocardiogram from required to suggested; and 5) adding a complete annual physical exam. The recommendations for semiannual chronic blood sugar control surveillance, annual retinopathy surveillance, seasonal influenza vaccination, and a once in a lifetime pneumococcal vaccination remained unchanged. The attitudes of the practitioners toward the revised guidelines were collected in a second survey. Further modifications to the guidelines were again made by collaboration between the specialist and the opinion A final version of the guidelines was distributed to faculty clinicians for review one week prior to a scheduled group discussion. Presentation of the revised guidelines at this meeting by the opinion leader resulted in a general acceptance of the guidelines minor additional modifications. modifications were 1) changing renal surveillance from dipstick urinalysis to an annual urine protein determination, and 2) changing the expectation for compliance with guidelines from all encounters to only those encounters in which diabetes was specifically addressed. The revised guidelines were then presented to the family medicine residents' practice management meeting for a discussion facilitated by the opinion leader. Resident endorsement of the guidelines was thereby also obtained without further modification. The total process of obtaining faculty and resident consensus with the guidelines took three months to complete.

Table 1. Results of Initial Survey of Clinician Practice Patterns

RECOMMENDATION	AGREE		DISAGREE	STRONGLY DISAGREE	NO OPINION	COMMENTS
1. Foot Examination Every Visit	6	(33%)	9	3	0	10
2. Semiannual Surveillance of Control*	12	(67%)	4	2	0	7
3. Annual Urinalysis	16	(89%)	0	1	1	0
4. Annual Lipid Panel	8	(50%)	8	0	2	7
5. One-time Baseline EKG	11	(61%)	5	0	2	3
6. Annual Ophthalmologic Exam	17	(94%)	1	0	0	3
7. Seasonal Influenza Vaccine	17	(94%)	0	0	1	0
8. One-time Pneumococcal Vaccine	17	(94%)	0	0	1	0

<sup>\*</sup> indicates monitoring of chronic blood glucose control with hemoglobin A1c or glycosylated hemoglobin assays

### **DISCUSSION**

This paper outlines a model process through which published guidelines for diabetes care were adapted to an academic primary care practice for subsequent electronic implementation. Several aspects of this approach facilitated guideline acceptance. Involvement of a specialist provided familiarity with published guidelines and access to the relevant scientific literature supporting them. Optimally, as in this case, the specialist should be known to and accepted by the practitioners to minimize the perception of an outside expert attempting to dictate practice. In this model, the practice opinion leader's involvement helped to defuse the practitioners' fears that they were being subjected to the control of a specialist. The opinion leader also was the specialist's focus for presentation of scientific literature, and streamlined the process of modifying the guidelines by collaborating with the specialist as the representative for the practice. Modifications were made efficiently without the need for time consuming group discussion yet without loss of the practitioners' sense of involvement in the decisions. The surveys were useful for rapid feedback from a high percentage of individuals. They allowed clinicians to have input individually, and to express views which they might not have voiced in a public forum. The surveys also promoted a sense of individual ownership of the process which facilitated the ultimate achievement of consensus. The surveys also allowed identification of individuals with strong disagreements who were then contacted by the specialist or the opinion leader in a one-on-one setting for discussion of the relevant scientific literature. Postponement of group discussion until the end of the process allowed much of the dissent to be resolved so that discussion could be focused on a few specific issues. It also optimized the likelihood of achieving consensus in a single meeting. Group process at this final meeting allowed remaining dissenters to discuss concerns with their colleagues and ultimately join the consensus opinion.

While other means of guideline implementation, such as a direct mandate for compliance, might have been more convenient and more reflective of the published guidelines, this consensus building model promoted willing compliance by addressing many of the barriers to guideline acceptance. It involved primary care clinicians in the adaptation process, reducing the perception of loss of clinical autonomy. Participation of the specialist introduced practitioners to published guidelines and the available scientific literature concerning the impact of guidelines on outcome and cost. Surveys allowed individual participation and facilitated a sense of personal ownership in the process. Group discussion allowed clinicians to air concerns about the flexibility of the guidelines in individual situations and provided

reassurance from colleagues that the guidelines were being established by the primary care clinicians themselves, not imposed by specialists.

There are several ramifications of the process of guideline consensus building used in this model. First, this study shows that guidelines established by expert panels will not necessarily be accepted by practicing clinicians verbatim. In this study, 50% of the guidelines would not have been supported by one third of the clinicians. This underscores the need for input from primary care clinicians in the guideline development process, the need to construct guideline recommendations from scientific data, and the need to allow regional or local practice modification of national guidelines where proven effectiveness of a recommendation is lacking. Short of such changes in the process of developing national guidelines, methods such as the approach described in this study will be needed to facilitate acceptance of guidelines. Second, this adaptation process will potentially lead to many sets of customized guidelines for individual practices. Such customization could be viewed as defeating the primary purpose of guidelines for standardizing care. In contrast, customization could be viewed as way to approaches evaluate alternative guideline to recommendations for which no "right way" has been scientifically demonstrated. Inclusion of a specialist in the adaptation process should ensure that only recommendations for which there is no compelling evidence for cost effectiveness are modified. Without customization, however, guidelines will potentially go unused or coercion will be required to effect compliance. Until the guideline development process routinely incorporates sound clinical evidence for cost effectiveness and accommodates the opinions representative of all clinicians using them, practicespecific adaptation of guidelines, as proposed in this paper, will be necessary to ensue compliance after electronic implementation.

In this study, a three-month period was needed to complete the guideline adaptation process. This time period could have potentially been decreased. The process was delayed by waiting for clinicians to return surveys and by the infrequency of practice meetings (monthly) for the initial presentation and final discussion of the guidelines. The process could have proceeded faster if clinician surveys were done by electronic mail and practice meetings were held more often.

In summary, medical informaticians should realize the critical importance of clinician acceptance of guidelines before meaningful study of the effect of computerization of guidelines can be done. The guideline adaptation model described in this paper was successful in achieving consensus among primary care clinicians regarding guidelines for continuing care of patients with diabetes mellitus prior to their electronic implementation. This model should be further tested at other primary care sites and for guidelines for other disorders.

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### References

- 1. Field MJ, Lohr NK, eds. Clinical Practice Guidelines: Directions for a New Program. Washington, DC: National Academy Press; 1990.
- Audet AM, Greenfield S, Field M. Medical practice guidelines: current activities and future directions. Ann Intern Med. 1990; 113:709-714.
- Woolf SH. Practice guidelines: a new reality in medicine. I. Recent developments. Arch Intern Med. 1990; 150: 1811-1818.
- Leape LL. Practice guidelines and standards: an overview. Quart Review Bull. 1990; 16:42-49.
- Gorton TA, Cranford CO, Golden WE, Walls RC, Pawelak JE. Primary care physicians' response to dissemination of practice guidelines. Arch Fam Med. 1995; 4:135-142.
- 6. Kosecoff J, Kanouse DE, Rogers WH, McCloskey L, Winslow CM, Brook RH. Effects of the National Institutes of Health Consensus Development Program on physician practice. *JAMA*. 1987; 258:2708-2713.
- Headrick LA, Speroff T, Pelecanos HI, Cebul RD. Efforts to improve compliance with the national cholesterol education program guidelines: results of a randomized controlled trial. Arch Intern Med. 1992; 152:2490-2496.
- 8. Haynes RB, Walker CJ. Computer-aided quality assurance: a critical appraisal. *Arch Intern Med.* 1987; 147:1297-1301.
- Grimshaw JM, Russell IT. Effect of clinical guidelines on medical practice: a systematic review of rigorous evaluations. *Lancet*. 1993; 342:1317-1322.
- 10. Johnson ME, Langton KB, Haynes RB, Mathieu A. Effects of computer-based clinical decision support systems on clinician performance and patient outcome: a critical appraisal of research. Ann Intern Med. 1994; 120:135-142.
- 11.McDonald CJ, Hui SL, Smith DM, Tierney WM, Cohen SJ, Weinberger M, McCabe GP. Reminders to physicians from an introspective computer medical record: a two-year randomized trial. Ann Intern Med. 1984; 100:130-138.
- 12. McDonald CJ. Protocol-based computer reminders, the quality of care and the non-perfectibility of man. *N Engl J Med.* 1976; 295:1351-1355.
- 13. Lobach DF, Hammond WE. Development and evaluation of a computer-assisted management protocol (CAMP): improved compliance with care

- guidelines for diabetes mellitus. Proceed Symp Comput Applic Med Care. 1994; 18: 787-791.
- 14. Evans RS, Hulse RK, Gardner RM, et al. Computer surveillance of hospital-acquired infections and antibiotic use. JAMA. 1986;256:1007-1011.
- 15.Lomas J, Anderson GM, Dominick-Pierre K, Vayda E, Enkin MW, Hannah WJ. Do practice guidelines guide practice? The effect of a consensus statement on the practice of physicians. N Engl J Med. 1989; 321:1306-1311.
- 16.McDonald CJ, Wilson GA, McCabe GP. Physician response to computer reminders. JAMA. 1980; 244:1579-1581.
- 17. Ellrodt AG, Conner L, Riedinger M, Weingarten S. Measuring and improving physician compliance with clinical practice guidelines: A controlled interventional trial. Ann Intern Med. 1995; 122:277-282.
- 18. Lomas J, Haynes RB. A taxonomy and critical review of tested strategies for the application of clinical practice recommendations: from "official" to "individual" clinical policy. Am J Prev Med. 1988; 4:77-94.
- 19. Tunis SR, Hayward RSA, Wilson MC, Rubin HR, Bass EB, Johnston M, Steinberg EP. Internists' attitudes about clinical practice guidelines. Ann Intern Med. 1994; 120:956-963.
- 20. Grol R. National standard setting for quality of care in general practice: attitudes of general practitioners and response to a set of standards. *Brit J Gen Prac.* 1990; 40:361-364.
- 21. Kelly JT, Swartwout JE. Development of practice parameters by physician organizations. *Qual Rev Bull.* 1990; 2:54-57.
- 22. Zyzanski SJ, Strange KC, Kelly R, et al. Family physicians' disagreements with the US Preventive Services Task Force recommendations. J Fam Prac. 1994; 39:140-147.
- 23. Delamonthe T. Wanted: guidelines that doctors will follow. *Brit J Med.* 1993; 307:218.
- 24. Vermeulen LC, Ratko TA, Erstad BL, Brecher ME, Matuszewski KA. A paradigm for consensus: the university hospital consortium guidelines for the use of albumin, nonprotein colloid, and crystalloid solutions. Arch Intern Med. 1995; 155:373-379.
- 25. American Diabetes Association. Standards of medical care for patients with diabetes mellitus. *Diabetes Care.* 1992; 15 (supplement 2): 10-13.
- 26. Turoff M. The policy Delphi. In: Linstone HA, Turoff M, eds. The Delphi Method: Techniques and Applications. Reading, MA: Addison-Wesley Publishing Company; 1975: 84-101.
- 27. Lomas J, Enkin M, Anderson GM, Hannah WJ, Vayda E, Singer J. Opinion leaders vs audit and feedback to implement practice guidelines. *JAMA*. 1991; 265:2202-2207.